

IN THE SUPERIOR COURT OF THE STATE OF DELAWARE

RICHARD SANTO,)	
Individually and as Personal)	
Representative of the Estate of)	
MARIAN SANTO,)	
)	
Plaintiff,)	
)	
v.)	C.A. No. K22C-07-014 NEP
)	
GENESIS HEALTHCARE, INC.,)	
)	
Defendant.)	

Submitted: February 24, 2023

Decided: May 16, 2023

MEMORANDUM OPINION AND ORDER

Upon Defendant's Motion to Dismiss Based on PREP Act Immunity
DENIED

Upon Defendant's Motion to Dismiss for Failure to State a Claim
DEFERRED

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Attorney for Plaintiff.

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Defendant.

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Primos, J.

This is an action for medical malpractice and wrongful death brought on behalf of a nursing home resident who died after contracting COVID-19 early in the pandemic. Before the Court is a motion to dismiss invoking both Delaware’s two-year statute of limitations for medical negligence claims, pursuant to 18 *Del. C.* § 6856, and the immunity provision of the Public Readiness and Emergency Preparedness Act (hereinafter the “PREP Act”). The Court concludes 1) that the PREP Act does not bar suit based on the record before the Court and 2) that the plaintiff will be allowed to amend his complaint before the Court rules on the statute of limitations issue. Accordingly, Defendant’s motion to dismiss based on PREP Act immunity is **DENIED**, and decision on Defendant’s motion to dismiss for failure to state a claim is **DEFERRED**.

FACTUAL AND PROCEDURAL BACKGROUND¹

Richard Santo (hereinafter “Plaintiff”), acting as the personal representative of the estate of Marian Santo (hereinafter “Decedent”), has filed a four-count complaint against Genesis Healthcare, Inc., (hereinafter “Defendant”). The counts are medical malpractice, wrongful death, a survival action, and respondeat superior liability for the alleged negligence of Defendant’s employees. Decedent was a resident of a nursing home facility called Milford Center, which, for the purposes of this motion, will be treated as the same entity as Defendant.²

The Complaint alleges that, early in the COVID-19 pandemic, Defendant commingled presumptive-positive residents with asymptomatic residents, allowed employees to use the same personal protective equipment (“PPE”) when treating

¹ The facts herein are as alleged in the Complaint unless indicated otherwise.

² The Complaint alleges that Defendant is also known as Milford Center. *See* Compl. ¶ 3. Defendant, however, has indicated that it “is not the owner or licensed operator of the Milford Center facility” but is nonetheless basing “this motion on the facts alleged in the Complaint.” Def. Genesis Healthcare, Inc.’s Opening Br. in Support of its Mot. to Dismiss [hereinafter “Def.’s Opening Br.”] at 4 n.1.

presumptive-positive residents and asymptomatic residents, and housed up to four residents in shared rooms.³ Decedent was housed with a group of two or three roommates.⁴ Other allegations include inadequate staffing,⁵ failure to maintain or educate staff on policies and procedures to prevent the spread of COVID-19,⁶ and failure to follow various federal, state, and local guidelines.⁷ Finally, the wrongful death count includes allegations that Defendant disregarded Decedent's history of dysphagia and administered medications orally, and failed to administer intravenous medication in a reasonable period of time.⁸

Decedent started receiving treatment for symptoms including shortness of breath and coughing on April 3, 2020.⁹ A COVID test administered on April 6, 2020, came back positive.¹⁰ Decedent died on April 15, 2020, and the causes of death were identified as 1) COVID-19; 2) mild calorie malnutrition; and 3) cerebral aneurysm.¹¹ On March 9, 2022, Plaintiff sent a Notice of Intent to Investigate Medical Negligence Claims, which under 18 *Del. C.* § 6856(4) may be used to toll the statute of limitations for 90 days.¹² The Complaint was not filed until July 14, 2022, two years and 99 days from the date the COVID-19 test was administered and two years and 90 days from the date of Decedent's death.

Defendant moved to dismiss the complaint pursuant to Superior Court Civil

³ Compl. ¶¶ 32(b–d) and 37(g–i).

⁴ *Id.* ¶ 20.

⁵ *Id.* ¶ 32(h).

⁶ *Id.* ¶ 32(e–g).

⁷ *Id.* ¶ 32([j]). Paragraph 32 contains two subparagraphs (g), but the Court refers to the second one, between subparagraphs (i) and (k), as (j) to avoid ambiguity.

⁸ *Id.* ¶ 37(q–r).

⁹ *See id.* ¶¶ 22–24.

¹⁰ *See id.* ¶ 29 (“Defendant confirmed Plaintiff as being Covid-19 positive on April 6, 2020.”). Plaintiff’s brief clarifies that Decedent was tested for COVID-19 on April 6 and the positive result was not received until April 9. Pl.’s Br. in Opp’n to Def.’s Mot. to Dismiss [hereinafter “Pl.’s Br. in Opp’n”] at 15 and n.1.

¹¹ Compl. ¶ 30.

¹² *Id.* ¶ 14.

Rules 12(b)(1) and 12(b)(6) on September 15, 2022,¹³ and the Court granted leave to submit briefing on the motion. Defendant filed its opening brief on September 16, 2022,¹⁴ Plaintiff filed his answering brief on November 3, 2022,¹⁵ and Defendant filed a reply brief on November 30, 2022.¹⁶ The Court heard oral argument on February 24, 2023.

PARTIES' CONTENTIONS

Defendant has moved to dismiss on three separate grounds: 1) the two-year statute of limitations for medical negligence actions, pursuant to 18 *Del. C.* § 6856, has expired; 2) Defendant is immune from liability and suit under the PREP Act; and 3) the Complaint is too vague to state a claim upon which relief can be granted. Plaintiff argues 1) that the statute of limitations has not expired because the Complaint alleges continuous negligent treatment up until Decedent's death; 2) that the PREP Act does not apply because Decedent's death was not caused by the use or administration of any "covered countermeasure" within the meaning of the PREP Act; and 3) that leave to amend the Complaint should be granted if the Court concludes that the Complaint fails to state a claim.

STANDARDS OF REVIEW

When faced with a Rule 12(b)(1) motion to dismiss, the "burden of establishing the Court's subject matter jurisdiction rests with the party seeking the Court's intervention."¹⁷ The Court is not required to accept the plaintiff's factual allegations as true and may consider documents outside of the pleadings.¹⁸

¹³ Def.'s Mot. to Dismiss (D.I. 9).

¹⁴ Def.'s Opening Br. (D.I. 12).

¹⁵ Pl.'s Br. in Opp'n (D.I. 23).

¹⁶ Def. Genesis Healthcare, Inc.'s Reply Br. in Further Support of its Mot. to Dismiss (D.I. 26).

¹⁷ *CSP N3 Sponsor LLC v. Grossman*, 2023 WL 2445345, at *2 (Del. Super. Mar. 9, 2023) (quoting *Donofrio v. Peninsula Healthcare Servs., LLC*, 2022 WL 1054969, at *2 (Del. Super. Apr. 8, 2022)).

¹⁸ *Id.*

When the Court considers a Rule 12(b)(6) motion, however, “(i) all well-pleaded factual allegations are accepted as true; (ii) even vague allegations are well-pleaded if they give the opposing party notice of the claim; (iii) the [c]ourt must draw all reasonable inferences in favor of the non-moving party; and [(iv)] dismissal is inappropriate unless the plaintiff would not be entitled to recover under any reasonably conceivable set of circumstances susceptible of proof.”¹⁹ The Court is limited to the allegations in the complaint and documents incorporated therein, and may also “take judicial notice of ‘matters that are not subject to reasonable dispute.’”²⁰

DISCUSSION

Defendant raises PREP Act immunity as a defense under both Rule 12(b)(1) and Rule 12(b)(6). These are different rules that serve different functions. A Rule 12(b)(1) motion calls into question the Court’s subject matter jurisdiction, i.e., its authority to grant the relief requested, whereas a Rule 12(b)(6) motion tests the sufficiency of the allegations in the Complaint, i.e., whether the plaintiff has pleaded a cognizable claim.²¹ As the above standards of review indicate, the standards governing a Rule 12(b)(1) motion are less favorable to the plaintiff.²² In addition, when considering a single motion to dismiss on both 12(b)(1) and 12(b)(6) grounds,

¹⁹ *Hammer v. Howard*, 2021 WL 4935019, at *2 (Del. Super. Oct. 22, 2021) (alterations in original) (quoting *Savor, Inc. v. FMR Corp.*, 812 A.2d 894, 896–97 (Del. 2002)).

²⁰ *Id.* (quoting *In re Gen. Motors (Hughes) S’holder Litig.*, 897 A.2d 162, 169 (Del. 2006)).

²¹ *See Appriva S’holder Litig. Co., LLC v. EV3, Inc.*, 937 A.2d 1275, 1285 (Del. 2007) (“[W]here a party is not arguing that the court lacks the authority to grant the relief requested to any plaintiff (i.e., lacks subject matter jurisdiction), but rather is arguing that the court cannot grant relief to these particular plaintiffs, the motion is more properly decided under Rule 12(b)(6) because the plaintiff has failed to plead a necessary element of a cognizable claim, not because the court does not have jurisdiction.”).

²² As the Third Circuit has explained with respect to similar federal rules, “Rule 12(b)(1) does not provide plaintiffs the procedural safeguards of Rule 12(b)(6), such as assuming the truth of the plaintiff’s allegations.” *CNA v. United States*, 535 F.3d 132, 144 (3d Cir. 2008), *as amended* (Sept. 29, 2008).

the Court should generally “consider dismissal on the jurisdictional ground first, ‘for the obvious reason that if the court lacks jurisdiction to hear the case then a fortiori it lacks jurisdiction to rule on the merits.’”²³

In light of those distinctions, the Court finds it appropriate to address, at the outset, whether immunity under the PREP Act is a jurisdictional bar properly analyzed under Rule 12(b)(1). Delaware courts have treated other forms of immunity from suit, such as sovereign immunity or immunity under the State Tort Claims Act, as implicating subject matter jurisdiction.²⁴ That the PREP Act provides immunity from suit (and not just from liability) further supports conducting a 12(b)(1) analysis.²⁵ Moreover, several state courts that have dismissed claims based on the PREP Act have done so on jurisdictional grounds.²⁶

Overall, the Court is inclined to agree that PREP Act immunity is

²³ *Watson v. Dep’t of Servs. for Children, Youths & Their Families Delaware*, 932 F. Supp. 2d 615, 619 (D. Del. 2013) (quoting *Mortensen v. First Fed. Sav. & Loan Ass’n*, 549 F.2d 884, 895 n.22 (3d Cir. 1977)); see also *Abbott v. Vavala*, 2022 WL 453609, at *5 (Del. Ch. Feb. 15, 2022) (“The Court must first address the Rule 12(b)(1) motion to dismiss for lack of subject matter jurisdiction because it raises a potentially dispositive threshold issue.”), *aff’d*, 284 A.3d 77 (Del. 2022) (TABLE); cf. *Branson v. Exide Elecs. Corp.*, 625 A.2d 267, 268–69 (Del. 1993) (holding that a trial court should address questions of personal jurisdiction before deciding a 12(b)(6) motion because a “court without personal jurisdiction has no power to dismiss a complaint for failure to state a claim”).

²⁴ See, e.g., *Laws v. Handy*, 2017 WL 3127783, at *4 (Del. Super. July 21, 2017) (“The Court finds that the Motion to Dismiss must be granted as to the Licensing Entity pursuant to Rule 12(b)(1) and the doctrine of sovereign immunity.”); *Janowski v. Div. of State Police Dep’t of Safety & Homeland Sec.*, 2009 WL 537051, at *2 (Del. Super. Feb. 27, 2009) (“Subject matter jurisdiction includes sovereign immunity cases.”), *aff’d sub nom. Janowski v. Div. of State Police, Dep’t of Safety & Homeland Sec., State*, 981 A.2d 1166 (Del. 2009); *Malachi v. Sosa*, 2011 WL 4348052, at *3 (Del. Super. Aug. 30, 2011) (dismissing claims against state officials for lack of subject matter jurisdiction because the officials were “immune from suit under the State Tort Claims Act”).

²⁵ See *Giovenco-Pappas v. Berauer*, 179 N.E.3d 815, 823 (Ill. App. Ct. 2020) (explaining that statutory immunity from *liability* is “not jurisdictional in nature” but that immunity from *suit* is jurisdictional).

²⁶ See, e.g., *Parker v. St. Lawrence Cnty. Pub. Health Dep’t*, 954 N.Y.S.2d 259, 263 (App. Div. 2012) (“[W]e conclude that plaintiff’s state law claims for negligence and battery are preempted by the PREP Act and, inasmuch as the exclusive remedy under the statute is a federal cause of action to be brought in federal court, **the complaint must be dismissed for lack of subject matter**

appropriately raised on a 12(b)(1) motion to dismiss and will assume so *arguendo* for the purposes of deciding this motion. However, courts have generally held that where, as here, “the jurisdictional facts are intertwined with the facts central to the merits of the dispute, it is the better view that . . . the entire factual dispute is appropriately resolved only by a proceeding on the merits.”²⁷ Moreover, in such cases, trial courts “must demand ‘less in the way of jurisdictional proof than would be appropriate at a trial stage.’”²⁸ Finally, federal courts recognize a distinction between a facial attack and a factual attack to subject matter jurisdiction. A challenge is facial, where, as here, “a motion to dismiss is filed prior to an answer and asserts that the complaint is jurisdictionally deficient on its face.”²⁹ On a facial challenge, a trial court construes all allegations in the complaint as true, as it would in addressing a 12(b)(6) motion.³⁰ Especially in light of these considerations, the same result obtains under either Rule 12(b)(1) or 12(b)(6)—for the reasons explained in Part I below, Defendant is not entitled to dismissal under the PREP Act at this stage of the litigation.

Since the PREP Act does not bar suit, the Court must also consider Defendant’s alternate grounds for dismissal under Rule 12(b)(6). However, for the

jurisdiction.” (emphasis supplied)); *Mills v. Hartford Health Care Corp.*, 2021 WL 4895676, at *5 (Conn. Super. Ct. Sept. 27, 2021) (“Finally, the court concludes that **the PREP Act provides immunity from suit** because those are the express words of the statute. . . . Claims based on the defendants’ acts or omissions . . . are **dismissed for want to jurisdiction** [sic].” (emphasis supplied)).

²⁷ *Appriva*, 937 A.2d at 1285 (omission in original) (quoting *Nesbit v. Gears Unlimited, Inc.*, 347 F.3d 72, 78 n.5 (3d Cir. 2003)).

²⁸ *CNA*, 535 F.3d at 144 (quoting *Gould Elecs. Inc. v. United States*, 220 F.3d 169, 178 (3d Cir. 2000)).

²⁹ See *United States v. Gilead Scis., Inc.*, 515 F. Supp. 3d 241, 248 (D. Del. 2021); *Constitution Party of Pennsylvania v. Aichele*, 757 F.3d 347, 357 (3d Cir. 2014) (“A district court has to first determine, however, whether a Rule 12(b)(1) motion presents a ‘facial’ attack or a ‘factual’ attack on the claim at issue, because that distinction determines how the pleading must be reviewed.”); *CNA*, 535 F.3d at 139.

³⁰ See *Aichele*, 757 F.3d at 358; *Gilead Scis., Inc.*, 515 F. Supp. 3d at 248.

reasons explained in Part II below, the Court concludes that deferral of decision on those grounds is appropriate, pending an opportunity for Plaintiff to file an amended complaint.

I. PREP Act Immunity

The PREP Act provides that “a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.”³¹ This immunity “applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure.”³² Where PREP Act immunity is applicable, any conflicting state law cause of action is pre-empted by the federal immunity defense.³³ Plaintiff concedes that Defendant is a covered person within the meaning of the statute,³⁴ so the issue before the Court is whether Plaintiff’s claims are caused by, arise out of, relate to, or result from the administration or use of a covered countermeasure.

A covered countermeasure is defined by statute to include 1) “a qualified pandemic or epidemic product”; 2) “a security countermeasure”;³⁵ 3) a “drug”, “biological product”, or “device that is authorized for emergency use”; and 4) “a respiratory protective device that is approved by the National Institute for

³¹ 42 U.S.C. § 247d-6d(a)(1).

³² *Id.* § 247d-6d(a)(2)(B).

³³ See *Maglioli v. All. HC Holdings LLC*, 16 F.4th 393, 406 (3d Cir. 2021) (“Federal preemption is a defense to state-law claims.”); *Parker*, 954 N.Y.S.2d at 144 (“Congress intended to preempt all state law tort claims arising from the administration of covered countermeasures by a qualified person pursuant to a declaration by the Secretary . . .”).

³⁴ Pl.’s Br. in Opp’n at 17 (“Plaintiff concedes that Defendant is a ‘covered person’ pursuant to PREP, likely as a program planner and a qualified person.”).

³⁵ A “security countermeasure” must be a drug, biological product, or device meeting the criteria set forth in 42 U.S.C. § 247d-6b(c)(1)(B).

Occupational Safety and Health and that the Secretary determines to be a priority for use during a public health emergency.”³⁶ In March of 2020, the Secretary of the U.S. Department of Health and Human Services issued a declaration under the PREP Act identifying COVID-19 as a public health emergency.³⁷ Through that declaration and seven subsequent amendments, the Secretary designated a wide variety of products as covered countermeasures.³⁸ An exhaustive list of what qualifies as a covered countermeasure would be too extensive to compile, but for the purposes of this case, it suffices to say that the list is expansive and includes devices used to diagnose COVID-19 (e.g., COVID tests or even thermometers) and PPE used to mitigate the spread of COVID-19 (e.g., masks and gowns).

PREP Act immunity is broad, extending not just to injuries directly caused by the use of a covered countermeasure but also to any claim “relating to” the administration to or use by an individual of a covered countermeasure. For example, courts have held that the PREP Act barred suit when a woman passed out and fell after being unable to find a chair in Walgreens after being administered a COVID vaccine³⁹ and when a parent brought a battery action for vaccination of her child without parental consent.⁴⁰ It does not, however, provide blanket immunity to a

³⁶ 42 U.S.C. § 247d-6d(i)(1).

³⁷ *Maglioli*, 16 F.4th at 401 (citing Declaration Under the PREP Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198, 15,201 (Mar. 17, 2020)).

³⁸ See Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, 85 Fed. Reg. 15,198, 15,202 (Mar. 2020) (covered countermeasures include “any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2”); Seventh Amendment to Declaration Under the PREP Act for Medical Countermeasures Against COVID-19, 86 Fed. Reg. 14,462 (Mar. 16, 2021).

³⁹ See *Storment v. Walgreen, Co.*, 2022 WL 2966607, at *3 (D.N.M. July 27, 2022) (“This chain of events is unfortunate and certainly deserving of a remedy, but it cannot be divorced from the administration of a covered countermeasure—the COVID-19 vaccine she received.”).

⁴⁰ See *Parker*, 954 N.Y.S.2d at 262–63 (“We are unpersuaded by plaintiff’s assertion that immunity pursuant to the PREP Act does not extend to qualified persons who administer a covered countermeasure to an individual without consent.”).

covered person (e.g., a facility) merely on account of that entity’s having used or administered covered countermeasures in order to prevent the spread of COVID-19. The plaintiff’s claim of injury must have some “causal relationship” to the use or administration of a covered countermeasure in order to trigger immunity.⁴¹

Mills v. Hartford Health Care Corp., a case out of the Superior Court of Connecticut, illustrates both the breadth and the limits of PREP Act immunity.⁴² In *Mills*, a woman went to the hospital and received test results consistent with both COVID-19 and another condition that indicated imminent danger of a severe heart attack.⁴³ She was administered a COVID test and isolated in the meantime to prevent the potential spread of COVID-19.⁴⁴ The test came back negative three days later at 7:40 p.m., and early the next morning she was to be transferred to the cardiac catheterization lab, but she died of a heart attack before the appointment.⁴⁵ The court ruled that the PREP Act provided immunity for claims “based on acts or omissions” prior to the negative test result at 7:40 p.m. “because such claims plainly are related to, and arise out of, a COVID-19 diagnostic counter measure, specifically, Ms. Mills’ COVID-19 test.”⁴⁶ However, the PREP Act did not provide immunity for acts or omissions from 7:40 p.m. on, “because, by that time, Ms. Mills’ COVID-19 diagnostic tests were at an end.”⁴⁷

There is only one published Delaware court decision construing the scope of PREP Act immunity. That case, *Hansen v. Brandywine Nursing & Rehabilitation Center, Inc.*, also came before this Court in the context of a suit against a nursing

⁴¹ 42 U.S.C. § 247d-6d(a)(2)(B).

⁴² 2021 WL 4895676 (Conn. Super. Sept. 27, 2021).

⁴³ *See id.* at *2–3.

⁴⁴ *Id.* at *3.

⁴⁵ *Id.*

⁴⁶ *Id.* at *4.

⁴⁷ *Id.*

home for alleged negligence in the early days of the COVID-19 pandemic.⁴⁸ In *Hansen*, the allegations were described as follows:

The Plaintiffs claim that BNR failed to properly hire, train, or direct staff as to the proper protocols to be followed in the face of the Pandemic. The Plaintiffs further allege that BNR failed to follow emergent CDC guidelines concerning hygiene, segregation and visitation, and were negligent in other respects that may be uncovered during discovery.⁴⁹

The Court, however, rejected the argument that these allegations related to the use or administration of covered countermeasures merely because “some countermeasure or another was used at the facility—thermometers, examination gowns, surgical apparel, etc.”⁵⁰ That argument, the Court reasoned, “confuses suits over the administration of a countermeasure itself—which is clearly immunized—with suits concerning prevention of infection.”⁵¹

At oral argument, Defendant’s counsel offered two lines of argument as to why the result in *Hansen* does not foreclose their argument here,⁵² contending (1) that *Hansen* is distinguishable on its facts because the complaint in that case did not relate to covered countermeasures⁵³ and (2) that *Hansen* is wrongly decided (or at

⁴⁸ 2023 WL 587950, at *1 (Del. Super. Jan. 23, 2023), *cert. denied*, 2023 WL 2199610 (Del. Super. Feb. 24, 2023), and *appeal refused*, 2023 WL 2544241 (Del. Mar. 16, 2023).

⁴⁹ *Id.* (internal footnotes and quotation marks omitted).

⁵⁰ *Id.* at *6.

⁵¹ *Id.*

⁵² The *Hansen* decision came down after briefing was completed but prior to oral argument in this case. The Delaware Supreme Court denied an application for interlocutory review on March 16, 2023. *Brandywine Nursing & Rehab. Ctr., Inc. v. Hansen*, 2023 WL 2544241 (Del. Mar. 16, 2023).

⁵³ See Tr. of Oral Arg. at 11:10–17 (“[T]he actual holding of *Hansen* was that the Complaint . . . was not about covered countermeasure[s]. So it may have been artfully pled, but the Complaint, itself, in the *Hansen* decision, was pled in terms of allegations about understaffing, for example, or the failure to implement policies related to COVID-19.”).

least contains overbroad dicta about the scope of immunity).⁵⁴

As to the first argument, Defendant is correct that the factual allegations here are not identical to the allegations in *Hansen*, although they certainly overlap with respect to inadequate staffing and the failure to follow proper protocols to prevent the spread of COVID-19. However (with the exception of the allegation regarding re-use of PPE), the allegations of negligence in this case share a key feature with the allegations in *Hansen*—they do not, on their face, mention any covered countermeasures. The defendant in *Hansen* attempted to recharacterize the complaint “as one about staff and resident screening practices as well as supplies and deployment of personal protective equipment.”⁵⁵ Likewise, in this case, Defendant tries to cast Plaintiff’s Complaint as alleging that Decedent died “as the result of allegedly negligent administration of infection control and countermeasure programs, including the use and administration of PPE, COVID-19 tests, and other related program planning decisions.”⁵⁶ Thus, the argument for PREP Act immunity in this case relies on the same inference rejected in *Hansen*—that general allegations of negligence leading to COVID-19 infection are so inherently intertwined with screening practices and PPE allocation that they must be claims of injury relating to the use of covered countermeasures (regardless of whether the complaint says so or not).

To take one specific example, Defendant argues that the allegation that presumptive-positive and asymptomatic residents were housed together must relate to a covered countermeasure because some countermeasure or another (e.g., a COVID-19 diagnostic test or thermometer) was most likely used to determine which

⁵⁴ See *id.* at 13:15–18 (“[T]o the extent that *Hansen* goes on to, I think, in dicta describe a very narrow definition of the scope of immunity, we would maintain that that that [sic] is wrongly decided.”).

⁵⁵ *Hansen*, 2023 WL 587950, at *6.

⁵⁶ Def.’s Opening Br. at 29.

patients were symptomatic or asymptomatic.⁵⁷ This line of argument, however, asks the Court to dismiss the Complaint based on facts and inferences outside of the Complaint or any other materials in the record before the Court.

Defendant also makes much of references to covered countermeasures in a document referred to in Plaintiff's complaint, a Department of Health and Human Services survey (hereinafter "the survey") documenting deficiencies in Milford Center's early COVID-19 response. However, the survey shows at most that Defendant did in fact use covered countermeasures early in the pandemic. For example, Defendant emphasizes an entry dated April 17, 2020 (two days *after* Decedent's death) explaining that staff used N95 respirators, face shields, gowns and goggles, and other PPE when interacting with presumptive-positive patients.⁵⁸ The survey does not, however, form the factual basis for Plaintiff's claims, and could not, given that the entire survey was conducted after Decedent's death. More importantly, it establishes only that covered countermeasures were in fact being used in the facility around the time of Decedent's death, not that Plaintiff's claim arises from or relates to their use or administration.⁵⁹

Defendant also takes issue with *Hansen's* "narrow" description of the scope

⁵⁷ See Tr. of Oral Arg. at 15:7–23 ("[T]he decision-making . . . about where to place symptomatic patients or Covid-positive patients, directly relates to use of diagnostic devices and tests within their infection control program. . . . [I]n the absence of Covid tests, the main type of symptom screening done is going to be temperature checks, which are done using thermometers, which are covered diagnostic devices used for persons -- the PREP Act.").

⁵⁸ See *id.* at 41:10–42:2; Def.'s Opening Br. Ex. C at 5.

⁵⁹ Cf. *Stone v. Long Beach Healthcare Ctr., LLC*, 2021 WL 1163572, at *5 (C.D. Cal. Mar. 26, 2021) ("Although Plaintiff mentions in her Complaint that Defendant was cited for not properly 'using' personal protective equipment three months *after* Decedent's death, there are no allegations linking Decedent's death to the *use* of that personal protective equipment or linking Decedent's death to the *purposeful* allocation of personal protective equipment to other individuals. Instead, Plaintiff appears to be merely using that citation as an example of Defendant's alleged failure to implement effective control policies in its facility.").

of immunity afforded under the PREP Act.⁶⁰ The Court agrees that “relating to” should be construed broadly,⁶¹ and may under some circumstances encompass claims of injury not directly caused by the use or administration of a covered countermeasure.⁶² Nevertheless, whatever else might have been said in dicta, the Court is persuaded by *Hansen*’s unequivocal rejection of the proposition that “[b]ecause some countermeasure or another was used at the facility—thermometers, examination gowns, surgical apparel, etc.” the suit necessarily relates to “the administration of countermeasures which are immunized by the PREP Act.”⁶³ That erroneous proposition is ultimately what Defendant’s argument boils down to, absent concrete evidence—beyond speculative inference—to connect Decedent’s death to the administration or use of a covered countermeasure.⁶⁴

⁶⁰ See Tr. of Oral Arg. at 13:15–18. Specifically, Defendant takes issue with statements in *Hansen* suggesting that “the PREP Act is primarily intended to address . . . claims that directly relate to injuries directly caused by countermeasures such as side effects of vaccines . . .” *Id.* at 13:20–22; see, e.g., *Hansen*, 2023 WL 587950, at *3 (“The immunity ensures that drug manufacturers will not be sued should the vaccine or other government-ordered countermeasure turn out to be defective or harmful.”).

⁶¹ Cf. *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992) (“For purposes of the present case, the key phrase, obviously, is ‘relating to.’ The ordinary meaning of these words is a broad one—‘to stand in some relation; to have bearing or concern; to pertain; refer; to bring into association with or connection with[.]’” (quoting Black’s Law Dictionary 1158 (5th ed. 1979))).

⁶² See, e.g., *Mills*, 2021 WL 4895676, at *4 (finding that claims of injury related to and arose from the administration of a COVID-19 test even though the test itself was not alleged to have harmed the plaintiff).

⁶³ *Hansen*, 2023 WL 587950, at *6; see also *Wilhelms v. ProMedica Health Sys., Inc.*, 205 N.E.3d 1159, 1166 (Ohio Ct. App. 2023) (reversing and remanding a trial court’s grant of judgment on the pleadings where the court’s “decision essentially treat[ed] the mere use of a ventilator/respirator, i.e., a covered countermeasure [sic], at various points of Wilhelms’ hospitalization as determinative evidence . . . that the loss or injuries caused[,] arose out of, related to, or resulted from the administration of or the use of the ventilator/respirator”).

⁶⁴ At oral argument, Defendant also invoked *Garcia v. Welltower OpCo Grp. LLC*, a federal court decision out of the Central District of California, in support of Defendant’s expansive reading of PREP Act immunity. 522 F. Supp. 3d 734 (C.D. Cal. 2021), *vacated and remanded sub nom. Garcia by & through Garcia v. Welltower Opco Grp. LLC*, 2022 WL 17077501 (9th Cir. Nov. 18, 2022). The District Court in *Garcia* found that claims fell within the scope of PREP Act immunity where the complaint “details infection control measures and procedures including symptom checking, staff monitoring and screening, and limiting visitation” and “directly draws

The Court notes one exception, however, which is the allegation that staff negligently used the same PPE when dealing with presumptive-positive and asymptomatic residents (the “PPE allegation”).⁶⁵ Most if not all forms of PPE meet the definition of a covered countermeasure.⁶⁶ Moreover, Plaintiff’s counsel effectively admitted at oral argument that the PPE allegation relates to the use by an individual (albeit not the individual who was allegedly harmed) of a covered countermeasure.⁶⁷ The Court will assume *arguendo* that the PPE allegation, standing on its own, would implicate PREP Act immunity.⁶⁸ In the context of the Complaint, however, it is one out of a long litany of allegations forming the basis for each count and does not on its own form an indispensable basis for any claim.

upon the use (and in some case [sic], misuse) of PPE.” *Id.* at 744. That case, however, has since been vacated by the Ninth Circuit in light of *Saldana v. Glenhaven Healthcare LLC*, in which that court held that the exercise of federal subject matter jurisdiction based on the doctrine of complete preemption was improper for PREP Act cases. 27 F.4th 679, 688 (9th Cir. 2022). While the District Court decision was vacated on jurisdictional grounds rather than on the basis of its immunity analysis, the two were closely related. *See Garcia*, 522 F. Supp. 3d at 746 (“Immunity applies for the same reason that the Court found the PREP Act conferred federal question jurisdiction.”). In light of this vacatur, and the reliance by the District Court in *Garcia* on Office of General Counsel advisory opinions called into doubt in *Saldana* and other federal court jurisprudence, *see, e.g., Maglioli*, 16 F.4th at 403–04, the Court finds the District Court decision in *Garcia* to be of little persuasive value.

⁶⁵ *See* Compl. ¶¶ 32(c) and 37(h).

⁶⁶ *See Martin v. Petersen Health Operations, LLC*, 37 F.4th 1210, 1213 (7th Cir. 2022) (“Face masks and other personal protective equipment are among the countermeasures defined by the Secretary . . .”).

⁶⁷ *See* Tr. of Oral Arg. at 29:4–12.

[The Court:] Wouldn’t the use or the allegation that the same PPE was used or reused with symptomatic and asymptomatic patients, wouldn’t that relate to a covered countermeasure?

Mr. Poliquin: I think the Prep Act, *although it relates*, it doesn’t -- it wouldn’t be protected since it’s not -- the allegations is [sic] that they didn’t administer those. [emphasis supplied].

⁶⁸ The language of the PREP Act appears broad enough on its face to cover this scenario, *see* 42 U.S.C. § 247d-6d(a)(1) (granting immunity from claims of loss “. . . relating to . . . the administration to or the use by an individual of a covered countermeasure . . .”), but the Court need not pre-commit itself to one reading or the other in any subsequent proceedings in this case.

Defendant is not entitled to a partial dismissal weeding out individual theories within a single claim.⁶⁹ So long as the case is allowed to go forward on each count, pruning out individual factual bases for each claim at this stage would do little to serve the statutory purpose of protecting defendants from suit. Defendant is free to seek summary judgment or other relief on those allegations, if appropriate, at a later stage in the proceedings.

In conclusion, the Complaint, at least on its face, does not fall within the scope of the PREP Act. Rather, like the complaint in *Hansen*, it alleges “ordinary” negligence in a variety of forms,⁷⁰ including housing residents in proximity (both symptomatic and asymptomatic), inadequate staffing, and failure to follow applicable guidelines to prevent the spread of infection.⁷¹ This result aligns with *Hansen* as well as other persuasive authority denying nursing homes PREP Act immunity when sued for alleged negligence during the COVID-19 pandemic.⁷² Nothing in this decision, however, precludes Defendant from re-raising the issue of PREP Act immunity after further factual development. Should additional facts come

⁶⁹ See *Unbound Partners Ltd. P’ship v. Invoys Holdings Inc.*, 251 A.3d 1016, 1028 (Del. Super. 2021) (“Delaware courts . . . allow 12(b)(6) motions for partial dismissal so long as they do not seek to just trim down theories within a single claim.”); *inVentiv Health Clinical, LLC v. Odonate Therapeutics, Inc.*, 2021 WL 252823, at *4 (Del. Super. Jan. 26, 2021) (“[A]t the pleading stage of a case, a trial judge is not a robed gardener employing Rule 12(b)(6) as a judicial shear to prune individual theories from an otherwise healthily pled claim or counterclaim.”). While these cases arose in the context of 12(b)(6) motions, the Court concludes that the same principle should apply to Defendant’s 12(b)(1) argument on the facts as alleged in this case.

⁷⁰ *Hansen*, 2023 WL 587950, at *8.

⁷¹ These as-of-yet unrebutted allegations are sufficient to meet Plaintiff’s jurisdictional burden.

⁷² See, e.g., *Arbor Mgmt. Servs., LLC v. Hendrix*, 875 S.E.2d 392, 397 (Ga. Ct. App. 2022) (denying PREP Act immunity to a nursing home where “the allegedly wrongful conduct is based on decisions made by [the defendant] regarding visitation, staffing, recreation, and socialization — conduct that has nothing to do with administration of a ‘covered countermeasure’ such as a drug, device, or other object as identified by HHS”); *McRedmond v. HCR Healthcare, LLC*, 2023 WL 1965052, at *2 (D. Del. Feb. 13, 2023) (denying PREP Act immunity where allegations included failure to adequately screen visitors and staff, failure to isolate patients, and failure to conduct COVID-19 screenings).

to light in discovery from which Defendant can argue that the alleged negligence was a byproduct of conscious decisions regarding PPE allocation or symptom screening based on covered diagnostic devices, the Court can address those arguments on the merits at that time with a firmer factual basis.

Accordingly, Defendant's motion to dismiss based on PREP Act immunity is **DENIED**, and Defendant's motion to dismiss for failure to state a claim can prevail only, if at all, on grounds other than PREP Act immunity.

II. Statute of Limitations

The statute of limitations for claims of medical negligence resulting in injury or death against a health-care provider is two years "from the date upon which such injury occurred."⁷³ The Delaware Supreme Court has held that the date the injury occurs is not the date the injury manifests, and is typically "the date when the wrongful act or omission occurred."⁷⁴ For the purposes of this case, Defendant has argued that the injury occurred when Decedent was infected with COVID-19, rather than on the date of her death. Since the COVID test was administered on April 6, 2020, that is the latest Decedent could have been infected with COVID-19, and thus, according to Defendant, the latest the statute of limitations could begin to run. Rather than disputing this point, Plaintiff (1) has argued that the Complaint states a claim of continuous negligent treatment⁷⁵ and (2) has suggested, for the first time at oral argument, that the statute of limitations might be tolled by the doctrine of

⁷³ 18 *Del. C.* § 6856. The same statute of limitations applies to wrongful death actions predicated on allegations of medical negligence because the wrongful death statute "imposes a condition precedent to the accrual of a wrongful death cause of action . . . , i.e., the decedent's ability to have maintained an action and recovered damages, if death had not ensued." *Drake v. St. Francis Hosp.*, 560 A.2d 1059, 1062 (Del. 1989).

⁷⁴ *Dunn v. St. Francis Hosp., Inc.*, 401 A.2d 77, 80 (Del. 1979); *but see GI Associates of Delaware, P.A. v. Anderson*, 247 A.3d 674, 685 (Del. 2021) (concluding that in "an unusual case" in which the injury occurred sometime after negligent medical advice was given that "the date of the negligent act and the occurrence of the injury do not coincide").

⁷⁵ See Pl.'s Br. in Opp'n at 13–15.

fraudulent concealment because Decedent’s family was not informed of her diagnosis until after her death.⁷⁶

“When there is a continuum of negligent medical care related to *a single condition* occasioned by negligence, the plaintiff has but one cause of action—for continuing negligent medical treatment” and the date of the injury is “the last act in the negligent medical continuum.”⁷⁷ However, a claim of continuous negligent medical treatment “during a finite period must be alleged in a Complaint with particularity” and “the facts in the record must establish that the treatment was inexorably related so as to constitute one continuing wrong.”⁷⁸ If those conditions are met, “the statute of limitations runs for two years from the date of [the] last act in the negligent continuum prior to actual knowledge or the point when a reasonably prudent person, in the exercise of reasonable diligence, could have discovered a prior continuous course of negligent medical treatment.”⁷⁹

While the bulk of the allegations in the Complaint relate to negligence leading to Decedent’s infection with COVID-19, the Complaint includes some post-infection allegations, including failing to advise Decedent or her family of her medical status, disregarding Decedent’s history of dysphagia and administering medications orally, and failing to administer intravenous medication in a reasonable period of time.⁸⁰ However, the “facts pled in support of” a claim of continuing negligent treatment “must be examined to see if the negligent treatment, as alleged, can be segmented or is, in fact, so inexorably intertwined that there is but one continuing wrong.”⁸¹ At this juncture, the Court is not persuaded by Plaintiff’s post

⁷⁶ See Tr. of Oral Arg. at 35:18–36:3.

⁷⁷ *Ewing v. Beck*, 520 A.2d 653, 662–63 (Del. 1987).

⁷⁸ *Id.* at 664.

⁷⁹ *Id.* at 665.

⁸⁰ Compl. ¶¶ 32(i) and 37(q–r).

⁸¹ See *Peck v. Orthopaedic Associates of Southerne Delaware, P.A.*, 2021 WL 3197549, at *3 (Del. Super. July 28, 2021) (quoting *Ewing*, 520 A.2d at 662).

hoc characterization of the Complaint as stating (with particularity) one continuing wrong, encompassing both Plaintiff's contraction of COVID-19 and her post-contraction treatment, resulting in her death. Moreover, the Complaint contains no allegations to support a claim of fraudulent concealment.⁸²

At oral argument, however, Plaintiff requested an opportunity to amend the Complaint "prior to any kind of dismissal."⁸³ Superior Court Civil Rule 15(a) provides that a "party may amend the party's pleading once as a matter of course at any time before a responsive pleading is served." No responsive pleading has yet been filed in this action, as a motion to dismiss does not qualify as such a pleading.⁸⁴ Accordingly, the Court will **DEFER** decision on Defendant's motion to dismiss for failure to state a claim and grant Plaintiff leave to amend his complaint.⁸⁵

CONCLUSION

Defendant's motion to dismiss based on PREP Act immunity is **DENIED**, but Defendant is not precluded from raising the PREP Act defense to liability after further factual development. The Court's decision on Defendant's motion to dismiss for failure to state a claim is **DEFERRED**. Within 21 days of this Opinion and Order, Plaintiff may file an amended complaint to add any facts supporting a claim for continuing negligent treatment or fraudulent concealment. Defendant shall then have 10 days to file a renewed motion to dismiss or may rest on its original motion and briefing if it so chooses. Following any such filings, or if no such submissions

⁸² See *Ewing*, 520 A.2d at 667 ("When a plaintiff wishes to rely on the doctrine of fraudulent concealment, a prerequisite is for the Complaint to allege that the health care provider had actual knowledge of the wrong done and acted affirmatively in concealing the facts from the patient.").

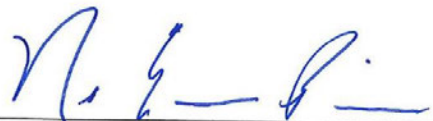
⁸³ See Tr. of Oral Arg. at 35:3–8; *id.* at 38:14–20; see also Pl.'s Br. in Opp'n at 21.

⁸⁴ See *Reylek v. Albence*, 2023 WL 142522, at *6 & n.51 (Del. Super. Jan. 10, 2023) (collecting prior Superior Court decisions to show that a "motion to dismiss is not a responsive pleading within the meaning" of Superior Court Civil Rule 15(a)).

⁸⁵ See *Peck*, 2021 WL 3197549, at *4 (Del. Super. July 28, 2021) ("[T]he Court will defer dismissal of Plaintiff's claims regarding pre-surgery diagnosis and will allow an additional amendment of the complaint as outlined at the close of this Opinion.").

are filed following the expiration of the 21-day period, the Court will issue a supplemental decision on Defendant's 12(b)(6) motion, addressing both the statute of limitations and pleading sufficiency issues.

IT IS SO ORDERED.


Noel Eason Primos, Judge

NEP:tls

Via File & ServeXpress

oc: Prothonotary

cc: Counsel of Record